SEP 2 8 2001

K000035

ADMINISTRATIVE INFORMATION

Manufacturer Name: Omnicare Dental Implant Center
One Rockefeller Plaza, #2221
New York, NY 10021

Official Contact: Robert Spalten, D.D.S.
Telephone (212) 355-6122
FAX (212) 262-3171

Representative/Consultant: Floyd G. Larson
PaxMed International
4329 Graydon Road
San Diego, CA 92130
Telephone (858) 792-1235
FAX (858) 792-1236

DEVICE NAME

Classification Name: Endosseous dental implant

Trade/Proprietary Name: Omnicare Dental Implant System

Common Name: Dental Implant

ESTABLISHMENT REGISTRATION NUMBER

Omnicare Dental Implant Center is registered with FDA under Establishment Registration Number 2437791.

DEVICE CLASSIFICATION

Endosseous dental implants have been classified by FDA as Class III devices under a final order published in the Federal Register of August 12, 1987, as shown in 21 CFR 872.3640. Abutments to such implants are considered by FDA to be Class III devices inasmuch as they are used as accessories to or are used with endosseous dental implants. The device is reviewed by the Dental Products Panel and the Product Code for the device is DZE.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards have been established under Section 514. Voluntary standards with which the Omnicare Dental Implant System complies include American Society for Testing and Materials (ASTM) designation F-136 (Standard Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications) and ANSI/AAMI/ISO 11137 (Sterilization of Health Care Products - Radiation Sterilization).

PACKAGING/LABELING/PRODUCT INFORMATION

Advertising material to be used for promotion of the Omnicare Dental Implant System will be consistent with the indications for use and other material shown herein.

Omnicare dental implants are packaged in a radiation sterilizable package consisting of an outer tamper evident container and an inner vial of glass or plastic. Sterilization is accomplished by means of Co^{60} gamma irradiation. The device is not represented to be "pyrogen free." Abutments and instruments will be packaged either sterile in a system similar to the implant packaging or non-sterile in plastic bags.

INTENDED USE

The Omnicare Dental Implant System is intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.

DEVICE DESCRIPTION

Design Characteristics

The Omnicare Dental Implant System is composed of a solid, grooved, tapered implant and a solid conical abutment, with associated instruments. The implant is a press-fit, two-stage design, incorporating a healing cap that seals the internal bore of the implant from the physiologic environment during healing. The healing cap is provided in three heights (1 mm, 2 mm, 3 mm) to allow either submerged placement or non-submerged, transmucosal placement. Non-submerged placement of the implant and healing cap will allow mucosal tissue to heal in conformance with the future position of the transmucosal portion of the abutment. The implant is available in two diameters and three lengths. Diameters are 4.4 mm and 3.6 mm. Each is available in lengths of 10 mm, 13 mm and 16 mm. The system includes surgical instruments such as drills, implant site dilators (osteotomes) and try-ins.

The system includes a solid conical abutment that is intended to be attached to the implant using a non-resorbable resin cement. Roughness of the internal bore of the implant and the post of the abutment ensures lifelong stability of the connection between the implant and abutment. The abutment is provided in either a straight configuration, or angled at 10° or 20° to the implant axis. The cemented design results in a firmly locking anti-rotational implant/abutment assembly, with a hermetically sealed joint between the implant and the abutment. The sealed joint prevents the ingress and egress of physiologic fluids and pathogens at the abutment/implant interface, such as may occur with screw-retained abutments. The coronal portion of the abutment is tapered at 3° per side and may be used with or without modification. A prosthesis may be fabricated by means of standard crown and bridge techniques for attachment to the abutment. The system also includes abutments for fixed-removable prosthesis attachment.

Material Composition

Implants and abutments for the Omnicare Dental Implant System are made from titanium-aluminum-vanadium alloy that meets ASTM designation F-136 (Standard Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications). Omnicare implants have a smooth machined collar of 2.5 mm height and from that point to the apex are are coated with a 50 μm thick layer of plasma-sprayed hydroxyapatite (HA) to facilitate attachment of bone. The use of titanium, titanium alloy and HA coatings is widespread in commercially distributed, permanently implanted medical devices and the materials are widely considered to be biocompatible. Titanium is often used as a negative control in biocompatibility testing.

EQUIVALENCE TO MARKETED PRODUCT

Omnicare Dental Implant Center submits the following information to demonstrate that the Omnicare Dental Implant System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices: the Bicon Dental Implant, the Steri-Oss Replace HA-Coated Implant, and the B.A.S.I.C. Dental Implant.

Intended Uses

The indications for use for the Omnicare Dental Implant System and the predicate devices are substantially the same. All are intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.

Design and Materials

The design and functional characteristics of the Omnicare Dental Implant System and the Bicon Dental Implant are similar in their use of a tapered, grooved design. The grooves are intended to provide macroretention in bone and to increase the surface area for bone attachment relative to a smooth design. The threads of the Steri-Oss Replace implant and the B.A.S.I.C. Dental Implant serve a similar function, and those implants also have a tapered design. The B.A.S.I.C. Dental Implant shares with the Omnicare Dental Implant the method of attaching the abutment to the implant using cement. The Omnicare implant shares the use of Ti-6Al-4V with the Bicon implant and numerous other marketed implants. It shares the use of an HA coating with the Bicon Dental Implant, the Steri-Oss Replace HA-Coated Implant and numerous other marketed implants..

Mechanical Testing of Omnicare Dental Implant System

In order to determine the strength of the Omnicare Dental Implant System, static and cyclic compression bending tests were conducted. Specimens were loaded to failure and maximum loads were recorded. This testing demonstrated that the static compressive strength and fatigue strength in bending, at the maximum angle at which the components are intended to be used, are significantly higher than normal forces of mastication.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP. 2 8 2001

Omnicare Implant Center, Inc.
C/O Mr. Floyd G. Larson
PaxMed International
4329 Graydon Road
San Diego, California 92130

Re: K000035
Trade Name: Omnicare Dental Implant System
Regulatory Class: III
Product Code: DZE
Dated: January 5, 2000
Received: January 6, 2000

Dear Mr. Larson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000035

Device Name: Omnicare Dental Implant System

Indications for Use:

Intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000035